

Notice of Allowability

Application No.

10/776,002

Applicant(s)

MITCHELL ET AL.

Examiner

Zachary C. Tucker

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 30 June 2006.
2. ☒ The allowed claim(s) is/are 1-33, 57 and 58.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date ____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date <u>30Jun06</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other ____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

After reviewing the amendment filed 30 June 2006, the examiner contacted applicants' counsel, Lauren L. Stevens, on 8 August 2006, requesting permission to cancel claims 34-36 and amend claim 33, as described hereinbelow. A voicemail message to this effect was left for Ms. Stevens. Later in the day, Ms. Stevens returned the call and left a voicemail message for the examiner in which she indicated that the proposed amendments would be acceptable to applicants.

IN THE CLAIMS –

Claim 33 has been amended as follows:

33. A pharmaceutical composition according to Claim 32, wherein the composition is formulated as an injectable fluid, an aerosol, a cream, a gel, a tablet[,] or a pill, a capsule, a syrup, an ophthalmic solution, or a transdermal patch.

Claims 34-36 have been **cancelled**.

The following further Examiner's Amendment, to the title of the application, is permitted as set out in MPEP 606.01.

IN THE SPECIFICATION –

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The title of the application has been changed to read as follows:

“Certain 8-(Heteroaryl/Phenyl)-6-(Phenyl/Pyridyl)-Imidazo[1,2-a]pyrazines as
Modulators of Kinase Activity”

end of amendments

Response to Amendment

As requested in the correspondence from applicants, filed 30 June 2006 (hereinafter "present amendment"), which is in reply to the Office action mailed 3 April 2006 (hereinafter "previous Office action"), claims 1 and 28-33 have been amended and claims 34-42 and 46-56 have been cancelled.

Election/Restrictions

Because the present amendment overcomes the rejections set forth in the previous Office action (*vide infra*), the claims in Group I, which was elected in response to the Requirement for Restriction mailed 4 January 2006, are in condition for allowance. Therefore the currently pending withdrawn claims, those claims from Group IV drawn to pharmaceutical compositions (withdrawn claims from restriction Groups II and III have been cancelled) are now rejoined and the Requirement for Restriction between chemical compounds *per se* – Group I – and pharmaceutical compositions comprising the same – Group IV – is hereby withdrawn.

Status of Claim Rejections - 35 USC § 112

In the previous Office action, claims 1 and 28-31 were rejected under 35 U.S.C. 112, first paragraph, for lack of a disclosure enabling the production of the claimed prodrugs of Formula (1) compounds.

In view of the present amendment, striking "and prodrugs" from claim 1, this rejection is hereby withdrawn.

In the previous Office action, claims 1-31, 57 and 58 were rejected under 35 U.S.C. 112, *second* paragraph, for indefiniteness of the term “prodrug” and “or form thereof.”

Since the offending language has been struck from the claims by virtue of the present amendment, the rejection of claims 1-31, 57 and 58 under 35 U.S.C. 112, *second* paragraph, is hereby withdrawn.

Specification

In the Requirement for Restriction mailed 4 January 2006, objection to the title of the application was set forth, on grounds that the title does not accurately describe the disclosed invention. Specifically, “8-Heteroaryl-6-Phenyl-Imidazo[1,2-a]pyrazines” as referred to in the title, are only part of the disclosed invention. Compounds according to the present invention are also 8-*Phenyl* substituted and 6-*Pyridyl* substituted. At the request of applicants’ counsel, the objection to the title was held in abeyance, pending allowance, as stated in the previous Office action.

The objection is hereby withdrawn in view of the amendment to the title in the attached Examiner’s Amendment. It is permissible for the examiner to amend the title of an application at allowance if he deems it appropriate to do so and applicants have not supplied such an amendment (MPEP 606.01).

Information Disclosure Statement

An Information Disclosure Statement has been submitted with the present amendment. Applicants’ counsel, in the remarks accompanying the present amendment, urges the examiner to consider the “lined through” references cited on the

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PTO 1449 form from the Information Disclosure Statements filed 5 November 2004 and 10 February 2005, noting that these references constitute "other information" within the meaning of 37 C.F.R. 1.98 and as such are not required to be cited with a publication date; "other information" are not publications. The examiner has now considered the references which were previously "lined through," A signed and initialed PTO 1449 form submitted with the Information Disclosure Statement of 30 June 2006 to that effect is enclosed herewith.

Upon review of these documents, the examiner feels it is important to note that it is unknown *how* they are relevant to the presently claimed invention. Because the cited documents are search reports and written opinions from foreign patent offices, the absence of the claims which formed the basis for said search reports and written opinions makes for an incomplete record. In other words, the information is meaningless without the claims which formed the basis for the opinions. Thus, the documents cited in the Information Disclosure Statement of 30 June 2006 have been viewed by the examiner, but not understood.

Allowable Subject Matter

Claims 1-33, 57 and 58 are allowed.

Reasons for allowance were provided on page 10 of the previous Office action.

Conclusion

All Post-Allowance Correspondence concerning this application must be mailed to:

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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Or you can fax them to the Office of Patent Publications at 703-872-9306, in order to expedite the handling of such correspondence as amendments under 37 CFR 1.312; information disclosure statements, and formal drawings. Sending Post-Allowance papers to Technology Center 1600 will only cause delays in matching papers with the case.

For information concerning status of correspondence sent after receipt of the Notice of Allowance, please contact the Correspondence Branch at (703) 305-8027. The Notice of Allowance also has an insert containing contact information on other items, including Issue Fees, receipt of formal drawings and the status of the application.
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A handwritten signature in dark ink, appearing to be "Z. L. H.", followed by a long horizontal flourish.